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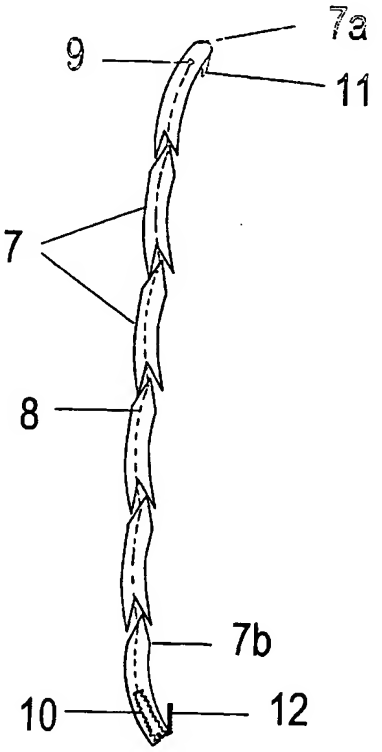
(54) Title: DEVICE FOR TREATMENT OF AN INSUFFICIENCY OF A HEART VALVE



(57) Abstract: The invention relates to a device for treatment of insufficiency of a heart valve comprising a longitudinal body (7-7) that can have at least two different forms, namely one easily introduced into the coronary sinus (5) or the great cardiac vein (vena cordis magna, 6) and to the vessel adaptable form, and a second one the position of the heart valve affecting form. The second form, when the longitudinal body (7-7) has been placed into the said vein, presses the vessel and thereby the orifice of the heart valve in parallel towards a closed position.

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Device for treatment of an insufficiency of a heart valve

The invention relates to a device for treatment of insufficiency of a heart valve.

The heart is anatomically two separate pumps working in series. While the right half of the heart (right ventricle) pumps the blood through the lungs against a relatively low pressure, the left ventricle pumps the blood against a high pressure through the other part of the body. Both sides consist of an atrium and a ventricle. The blood enters the heart via the atriae and continues into the respective ventricles.

Between the atrium and the ventricle there is a ring-shaped valve that prevents the blood from flowing back into the atrium. The valve on the right side is called the tricuspid valve and consists of three leaflets, while the mitral valve on the left side consists of two leaflets.

Due to the relation to the body one leaflet is called the anterior leaflet whereas the second one is called the posterior leaflet. The leaflets are connected to a fibrous ring-structure called the annulus. This part of the heart is made of a non-elastic connective tissue whereas the rest of the heart consists of heart muscle, responsible for the pump work.

Figure 1 shows a heart seen from above where the left and most of the right atrium have been removed. The aortic valve and the pulmonary valve are marked with (3) and (4), respectively.

The mitral valve (1) consists of the anterior leaflet (1a) and a posterior leaflet (1b) both connected to the annulus (1c). When blood enters the left ventricle from the atrium the valve closes during the contraction and prevents the blood from flowing back into the atrium. However, during the course of the life a small split (1d) between the leaflets may arise and a small amount of blood will leak backwards but will normally have no circulatory significance.

Figure 1 also shows the tricuspid valve (2) with its tree leaflets on the right side of the heart. In the atrium above the valve a vessel called the coronary sinus (5) has its outlet and function as a collector of the blood passing the heart muscle itself. The continuation of the vessel is called the great cardiac vein (vena cordis magna, 6). The coronary sinus follows a groove between the atrium and the ventricle on the left side located back on the outside of the heart. The figure also shows that it basically follows the posterior leaflet of the mitral valve.

Exercise results in an increased heart work including increased stroke volume and increased blood pressure. Increased stroke volume depends on an increased filling of the heart before the blood is ejected. Increased filling also leads to an increased force of the heart due to a specific property of the heart called the Frank-Starling mechanism. Also a sick heart makes use of the same mechanism even at rest. The cause might be a heart failure following a big infarction. If the increased filling of the heart continues over years, it will also have an impact on the connective tissue where the valve is connected. The annulus will dilate and the leaflets will become relatively too small to cover the whole orifice of the mitral valve. While the left ventricle develops a significantly higher pressure than the right ventricle, it is almost always the mitral valve and specifically the back part of the annulus that becomes dilated.

The result of the dilation is that blood leaks backwards at every contraction of the heart and the leakage is proportional to the opening between the two leaflets. Occasionally the opening can be so wide that a greater portion of the blood regurgitates into the atrium and prevents the transport of sufficient blood into the body.

The result of this is a pump failure that sometimes may be helped by drugs, but most of the case needs to be surgically repaired.

A surgical treatment of the mitral valve is a quite big operation and requires opening of the chest. It is often a question of

1. Replacing the native valve with a mechanical valve fitting the size of the annulus.
2. Mitral valve repair, for instance in a combination with a reinforcement of the annulus with help of a metal ring.

However, some people, mainly elderly are too weak to tolerate such an operation.

The development in the medical field has created techniques that miniaturise special treatment options. Several types of treatment are now possible with help of small catheters that are inserted into the body.

Narrowings of coronary arteries were earlier exclusively treated with open-heart surgery, whereas today most of these diseases are treated with help of small dilating balloon catheters if possible. The patients can be discharged within a few days after such treatment. Today there are also efforts made to try to treat patients with mitral valve leakage with catheter born technique.

It has earlier been described how the coronary sinus and the continuation of it, great cardiac vein follow the groove between the left atrium and ventricle and follow the posterior leaflet of the mitral valve.

If it were possible to get into that vessel and shorten the length of it one could imagine that the curvature of the annulus would become shorter. The result would be that the poste-

rior leaflet would be pushed forward and reduce an eventual valve leakage.

Technically it is easy to reach the coronary sinus with a catheter via vessels on the neck or in the groin. This technique is known and in use in many medical procedures. Therefore several devices have been invented that are aiming at treating mitral valve leakage through a placement in the coronary sinus.

The patent WO 02062270 is based on a construction where one or more stents are placed in the coronary sinus creating anchoring points. Between the distal and proximal stent on a stent between these, wires are connected and a shortening of the wires are aiming at reduce the length of the curvature and reduce the radius of the annulus. The result should be that the posterior leaflet would be pushed forward and closer to the anterior leaflet and thereby reduce the backward leakage according to the earlier argumentation.

Document DE 101 61 543 A1 discloses a ring consisting of chain of stiff elements connected by a wire. Each element fits into the neighbour element and has a central channel in the longitudinal direction. In this channel there is a wire fixed at the distal element. Through a screw-mechanism in the proximal element all elements can be joined together with a high force and form a solid ring that follows the inner curvature of the coronary sinus. The stiffness of the ring keeps the annulus in place and prevents the posterior leaflet slide back during the contraction of the heart and thereby prevents or reduces the leakage of the valve.

According to the present invention, a device for treatment of insufficiency of a heart valve is provided, comprising a longitudinal body that can have at least two different forms, namely one easily introduced into the coronary sinus or the great cardiac vein (vena cordis magna) and to the vessel adaptable form, and a second one the position of the heart valve affecting form, wherein the second form, when the longitudinal body has been placed into said vein, presses the vessel and thereby the orifice of the heart valve in parallel towards a closed position.

In contrast to the discussed prior inventions that aim at reducing the radius of the coronary sinus, the present invention aims at creating a bow consisting of several small elements.

The distal and the proximal elements create the two legs of the bow whereas the central part is created by the element in the middle.

The closed position can assume the form of a bow with a mainly straight central part between two legs that can have more or less the form of a bow.

Exemplary embodiments of the present invention are illustrated in the accompanying drawings, and will be described hereinafter with respect to the drawings, in which:

Fig. 1 schematically shows a top plan view of a heart;

Fig. 2 shows a device for treatment of insufficiency of a heart valve in an unstressed condition insertable into the body;

Fig. 3 shows the device in Fig. 2 in a stressed condition;

Fig. 4 shows another embodiment of a device for treatment of insufficiency of a heart valve in an unstressed condition insertable into the body;

Fig. 5 shows the device in Fig. 4 in a stressed condition;

Fig. 6 shows another embodiment of a device for treatment of insufficiency of a heart valve in an unstressed condition insertable into the body;

Fig. 7 shows the device in Fig. 6 in a stressed condition;

Fig. 8 shows another embodiment of a device for treatment of insufficiency of a heart valve in an unstressed condition insertable into the body;

Fig. 9 shows the device in Fig. 8 in a stressed condition;

Fig. 10 shows a portion of a device for treatment of insufficiency of a heart valve according to another embodiment, wherein the upper figure shows the elements of the device in an unstressed condition, and the lower figure shows the elements in a stressed condition;

Fig. 11 shows an illustration similar to Fig. 10 of another embodiment of a device for treatment of insufficiency of a heart valve;

Fig. 12 shows the device in Fig. 2 and 3 when inserted into the body in an unstressed condition of the device;

Fig. 13 shows the device in Fig. 12 inserted in the body in the final stressed condition;

Figs. 14 and 15 show a screw mechanism for stressing a device according to Figs. 1 through 11;

Fig. 16 shows further details of a screw mechanism for a device according to Figs. 1 through 11;

Fig. 17 shows another embodiment of a device for treatment of insufficiency of a heart valve in a lateral side view;

Fig. 18 shows the device in Fig. 17 in an end side view;

Figs. 19 and 20 show the device in Fig. 17 in a stressed condition;

Fig. 21 shows the device in Figs. 17 through 20 when inserted into the body.

With respect to Fig. 13, the proximal leg is fixed at the orifice of the coronary sinus (17) whereas the distal leg is fixed

distally in the coronary sinus or in the great cardiac vein (18). The central part of the bow is mainly in parallel to the opening between the two leaflets.

Figure 2 and 3 show a construction of the bow before it is inserted into the body whereas figure 12 shows the bow placed into the coronary sinus before the wire is tightened. Figure 13 shows the bow in the coronary sinus after the wire has been tightened and shows how the bow exerts a pressure against the inner curvature of the coronary sinus and thereby against the posterior mitral valve leaflet.

The bow is built up of separate elements lying in a row (7). The number of elements between the proximal (7b) and the distal one may vary.

In a channel through all elements there is a wire (8) that keeps the elements together like a chain. Figure 2 shows the wire fixed in the distal element while a screw at the proximal part of the wire (20) in a screw-mechanism makes it possible to tighten the elements against each other and create a stiff bow (Fig. 2, 14, 15). The elements are fitted to each other to form a solid bow with a smooth surface so that the guiding parts (13) between them disappear. The proximal and the distal element have one or more hooks (11, 12, fig.2) with the intention to grip on the inner curvature in the coronary sinus in order to fix the bow.

The bow can have different shapes according to the requirement regarding the size and form of the coronary sinus and the posterior leaflet in a specific patient.

Figure 2 and 3 show a shape of the bow where the distal and the proximal element deviate only little from the form of a even curve, whereas the figures 4, 5, 6, 7 and 8, 9 respectively show a bow where the two element form angled legs in relation to a straight central part.

Moreover the figures 4, 5, 8 and 9 show a connection between the proximal and next element and between the distal and the next element in form of a hinge.

To fix the elements to each other and to increase the strength of the ring several possibilities exist. Figure 10 shows wedge-shaped elements whereas figure 11 shows separate elements with a cone fitting into the previous element.

The final form of the bow depends on the shape of the separate elements and each separate element can have an individual construction and angle in relation to each other. To increase the flexibility of the bow and to easier manoeuvre it on the way from the groin and into the coronary sinus, the number of element can be increase.

The inner wire of the device (8) keeps the elements together and is located in a channel (8″) through all elements, figures 14 and 15.

The wire is fixed (9) at the distal element (fig. 2) and at the screw-mechanism (10) in the proximal element.

The fixation in the proximal element can be done with help of a fixation point (19) in a screw (20). Through a counter-clock

rotation (left) as shown in the figure 14 the screw will move out of the element as shown in figure 15. The result is that the wire will pull the elements together forming the bow.

The wire might be attached to a metal ball (19) that slides inside the screw to avoid the wire to twist or it can be fixed to the screw and follow the rotation of it during the employment.

The screw may contain a groove in which a pivot (23) on a special screw-catheter fits (figure 16). This catheter has a screw-head (21) with threads that fit into the screw-mechanism. The screw-head is connected to the distal end of a flexible shaft (24) located in a flexible sleeve (25).

Because the pivot on the screw-head fits into the groove in the screw-mechanism both the screw-head and the screw in the screw-mechanism will rotate when the flexible shaft rotates. The flexible shaft has its proximal end outside of the body. By means of the screw-catheter it is possible to rotate the screw in the screw-mechanism and deploy the device that has been positioned in the coronary sinus.

Another design is shown in figure 17 and is based on a bow-and-arrow principle. The body of the bow (26) consists of a relatively flexible material and has a straight shape, but can easily be bent forming a bow but can also easily be longitudinally twisted. On both ends there is a ring (27, 28) fixed and square to the body of the bow. On both rings, opposite to the attachment on the bow the wire of the bow is attached. This wire has the form of a band with a high longitudinal strength,

is flexible and can easily be twisted or bent. The distal attachment is fixed to the distal ring (28), whereas the fixation on the proximal ring (27) can be adjusted to the desirable length of the band, with help of a screw-mechanism as shown on figures 14 and 15.

When the device is outside of the body and the band is tightened, it will change from a straight for to a bow form (fig. 19) while the band will remain straight or light bowed near the attachments on the rings. When the device is manoeuvred into a vessel with the shape of a curve, both the body of the bow and the band will follow this curve (figures 20, 21).

The rings serve as the fixation points for the band, but also permit the blood to pass between the bow and the band. When the device is placed in the vessel, the body of the bow will follow the outer curvature and the band will follow the inner curvature of the coronary sinus.

Both rings can be equipped with one or more hooks (30, 31). These rings serve to grip into the inner curvature of the vessel and to reduce the force that arises between the ring and the body of the bow.

When the bow is bent the outside of its body will exert a pressure on the outer curvature of the vessel, whereas the band will exert a pressure against the inner curvature of the vessel and thereby indirectly push against the back side of the posterior leaflet of the mitral valve.

Arrows in figure 21 show the direction of the forces; the resulting force on the mitral valve is indicated with a bold arrow.

It is possible to use memory metal as a part of the device. A memory metal has the advantage that it assumes a certain configuration at a certain temperature. It would therefore be possible to configure the device to assume a certain form at 37 degrees Celsius. A memory metal like for instance nitinol may be used either in the body of the device or in the screw mechanism to deploy the device in the coronary sinus. An advantage of the memory metal is that it can reinforce the screw mechanism so that less force is needed for the deployment in the vessel.

The two referred publications mentioned above aim at bringing about a force along the coronary sinus to reduce the length of the vessel. This force needs to be relatively strong because of the high pressure that is created by the left ventricle and will therefore probably difficult to obtain.

The publication WO 02062270 anchors the stents in a vessel that anatomically is a vein that usually is thin and easily will burst when it is exposed to forces.

The present invention does not need to reduce the length of the coronary sinus. With help of its legs it is fixed to the inner curvature of the coronary sinus e.g. with help of small hooks that grips to the inner curvature of the vessel.

The central part of the device presses against the posterior leaflet of the mitral valve and does not need to develop a high force to do this.

The fixation of the device is made against the inner curvature of the vessel. This is a great advantage because the vessel rests against strong muscle and connective tissue. Should a bleeding happen due to the hooks on the inner curvature, this would be relatively harmless because the bleeding will occur inside the vessel.

Claims

1. A device for treatment of insufficiency of a heart valve comprising a longitudinal body (7-7) that can have at least two different forms, namely one easily introduced into the coronary sinus (5) or the great cardiac vein (vena cordis magna, 6) and to the vessel adaptable form, and a second one the position of the heart valve affecting form characterized in that the second form when the longitudinal body (7-7) has been placed into the said vein presses the vessel and thereby the orifice of the heart valve in parallel towards a closed position.

2. The device of claim 1, characterized in that the closed position can assume the form of a bow with a mainly straight central part between two legs that can have more or less the form of a bow.

3. The device of claim 1 or 2, characterized in that the body (7-7) consists of a number of separate preferably stiff elements (7).

4. The device of claim 3, characterized in that said elements are separate from each other.

5. The device of claim 3, characterized in that said elements are linked and articulated with one another.

6. The device of claim 4, characterized in that said elements are arranged in a row forming a chain whereby some and preferably all elements are provided with one to the next element guiding remedy (16) at their ends.

7. The device of anyone of claims 3 through 6, characterized by a wire or the like with help of which the elements (7) can be pulled against one another.

8. The device of anyone of claims 3 through 7, characterized in that mainly wedge shaped cavities exist between said elements (fig 4, 5 or 8, 9).

9. The device of claim 8, characterized in that the cavities within a central part of the longitudinal body of the device are essentially smaller than certain at the end of the body's positioned cavities, whereby the body through a longitudinal contraction forms a hoop with mainly a straight section between two legs that can be more or less formed like a bow.

10. The device of claim 7, characterized in that the wire (8) is fixed at the distal element and at the proximal element and that the proximal element has a tightening arrangement (10,19-21) by which the length of the wire (8) can be reduced between said elements.

11. The device of claim 7 or 10, characterized in that the wire is guided through a guiding arrangement preferably in all elements (7).

12. The device of claim 11, characterized in that the guiding arrangement consists of a through the element passing channel (8″).

13. The device of claim 12, characterized in that the channel (8″) and the wire (8) is such adjusted that only a limited

torsion possibility between two neighboring elements is possible for instance through a square form with slightly different dimensions or an oval form with slightly different dimensions.

14. The device of claim 6 characterized in that the said guiding remedy (13) consists of a conical part in one element fitting into an appropriate cavity (13) in the neighboring element (figure 3).

15. The device of anyone of claims 1 through 15, characterized in that the said valve (1) consists of the posterior mitral valve leaflet (1b).

16. The device of anyone of claims 2 through 15, characterized in that the two utmost elements (7a, 7b) are provided with a remedy, by which it can be locked in certain positions in relation to the coronary sinus and or the great cardiac veins, for instance hooks (11,12) that can attach to the inner wall of the vein and underlying tissue.

17. The device of claim 6 characterized in that the guiding remedy between two neighboring elements at each end or near their ends are formed like hinges whereby these elements can form an essentially right angle in relation to each other.

18. The device of anyone of claims 1 through 17, characterized in that it is constructed like a bow-and-arrow with a bow and a string which together can be introduced into the coronary sinus or the great cardiac vein and by separation of the string and bow influences the internal inner surface of the vein with the string and the internal outer surface of the vein with the bow.

19. The device of claim 18 characterized in that the separation is accomplished through a remedy for influencing the bow and/or the string for instance through shortening or a prolongation.

20. A method for treatment of a heart valve's insufficiency characterized in that the heart valve leaflets are pressed against each other with help of a device according to any of the preceding claims.

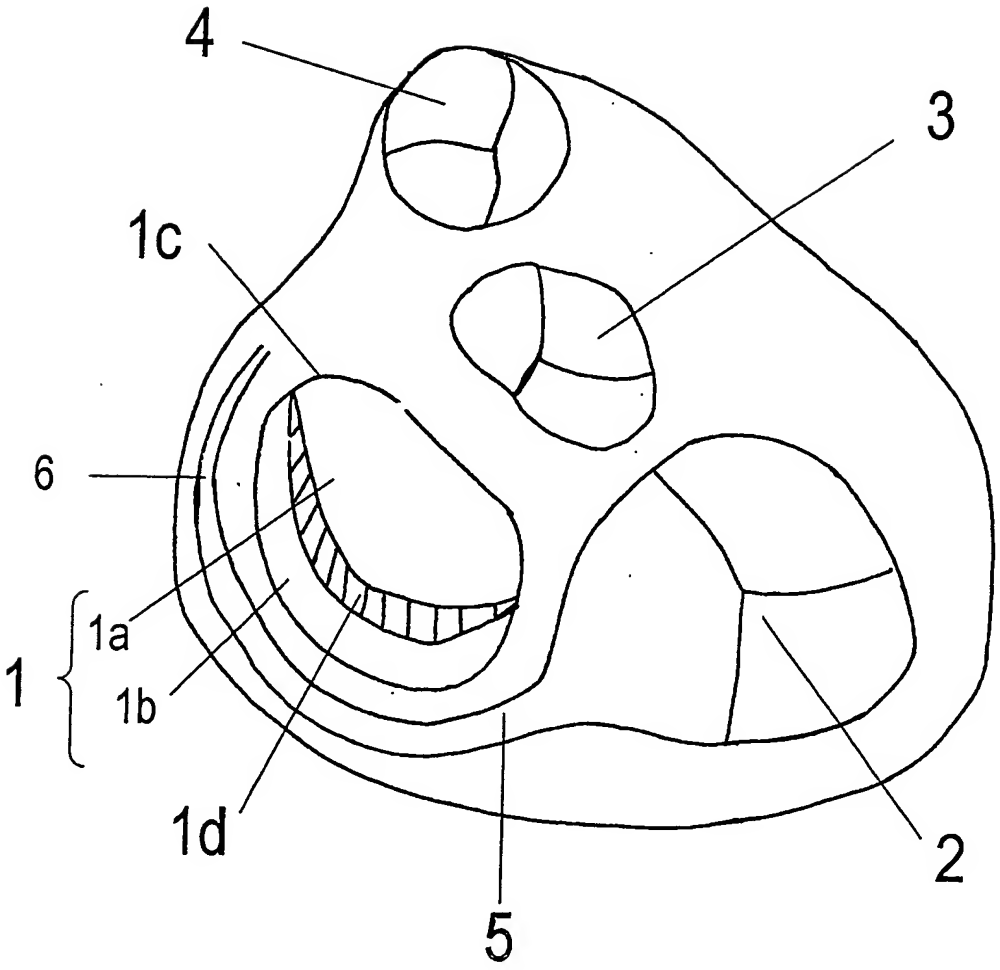

Fig. 1

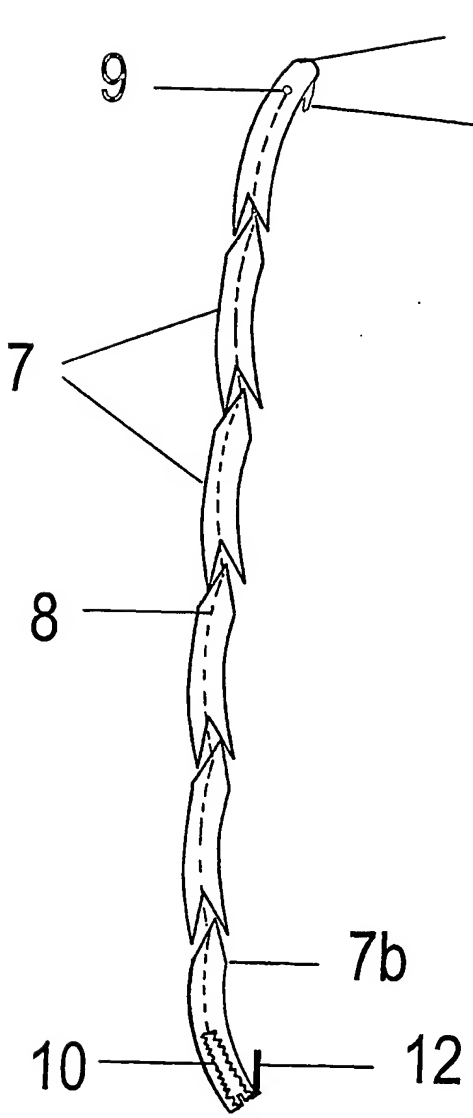

Fig. 2

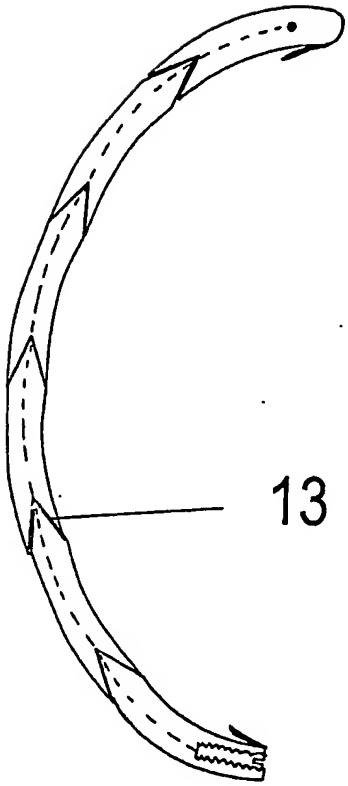

Fig. 3

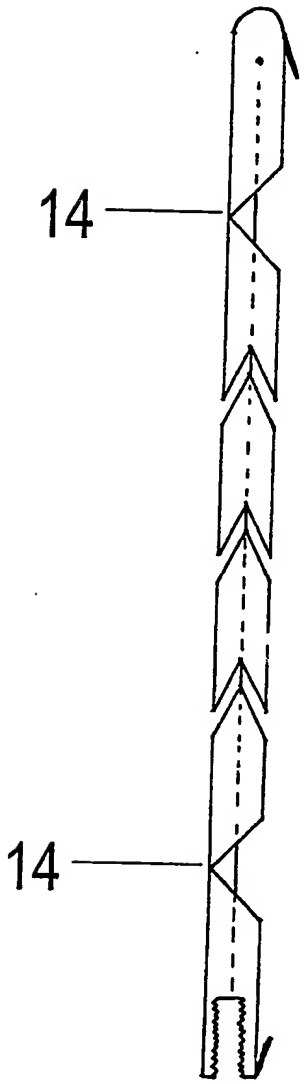

Fig. 4

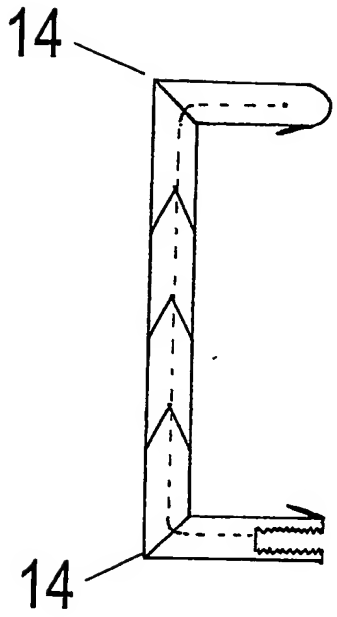

Fig. 5

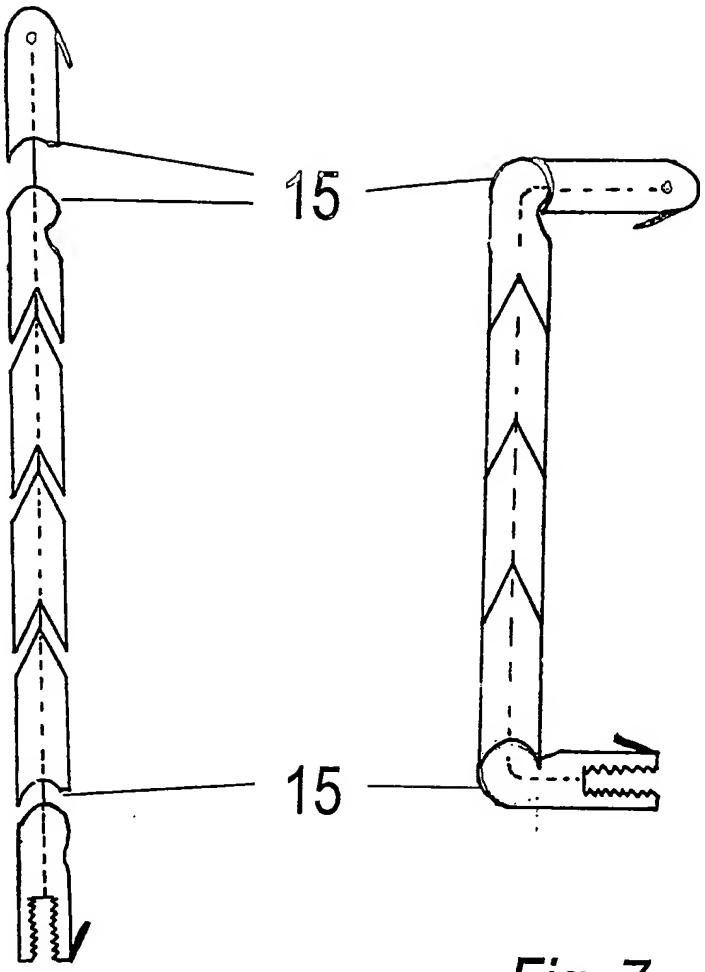

Fig. 7

Fig. 6

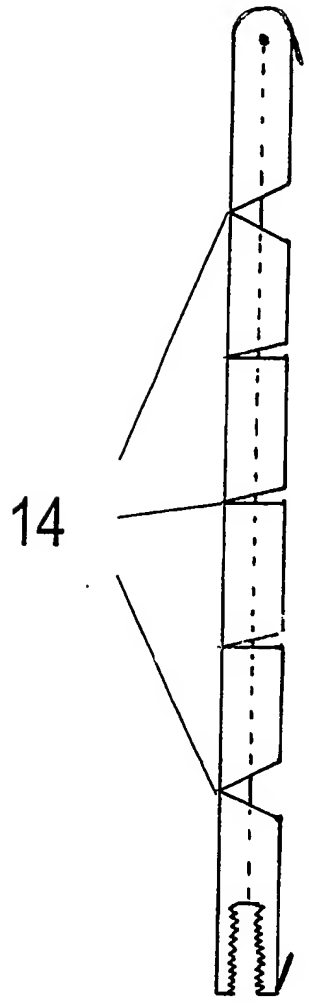

Fig. 8

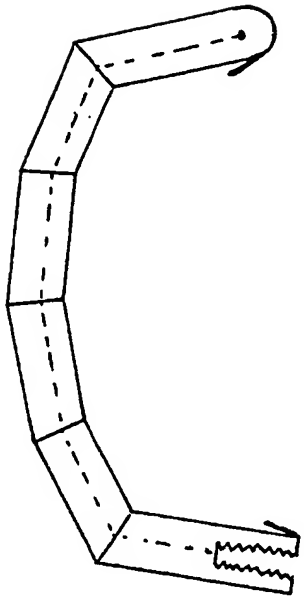

Fig. 9

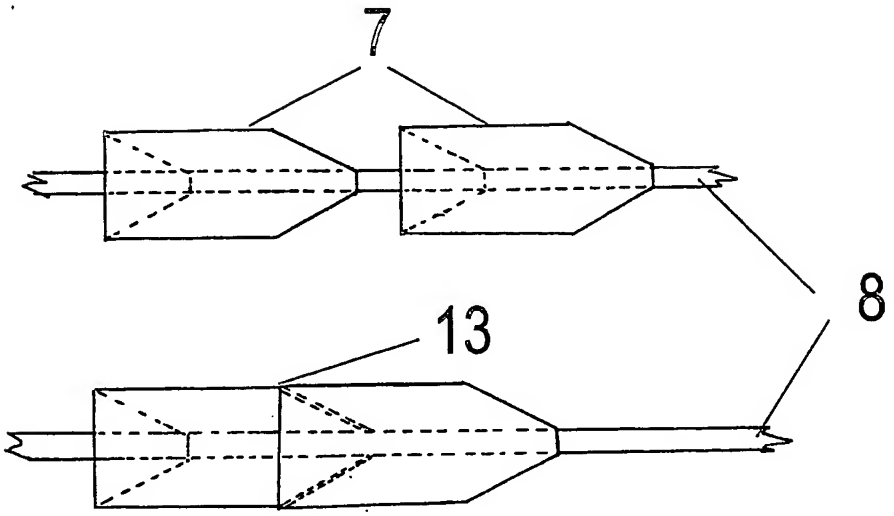

Fig. 10

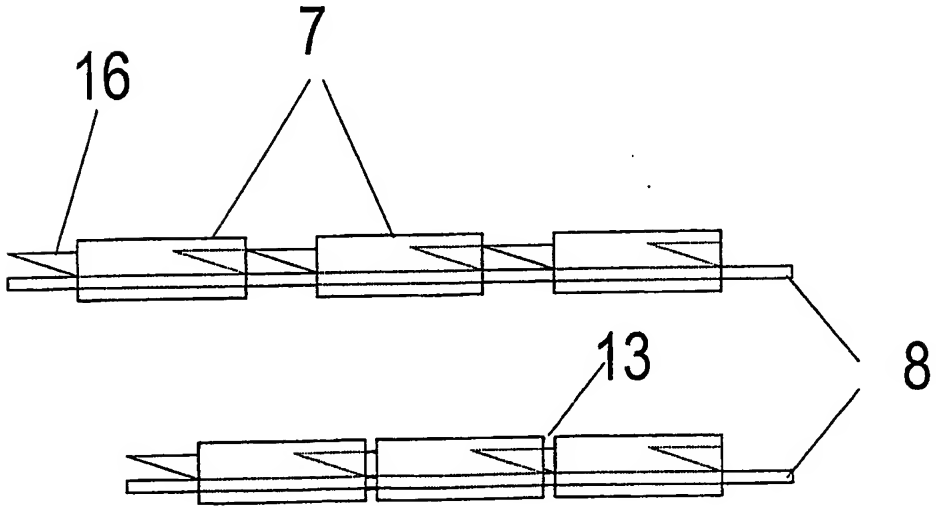

Fig. 11

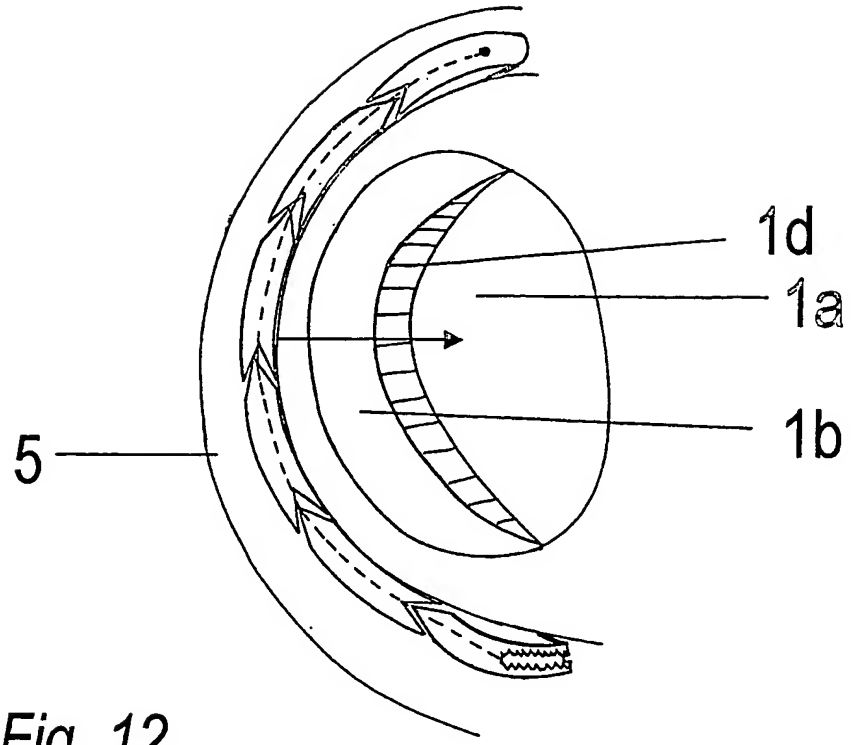

Fig. 12

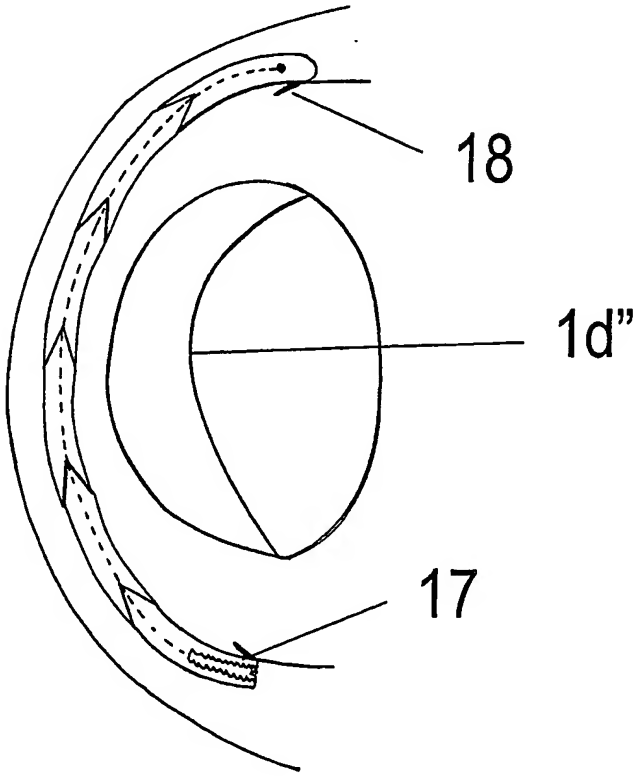

Fig. 13

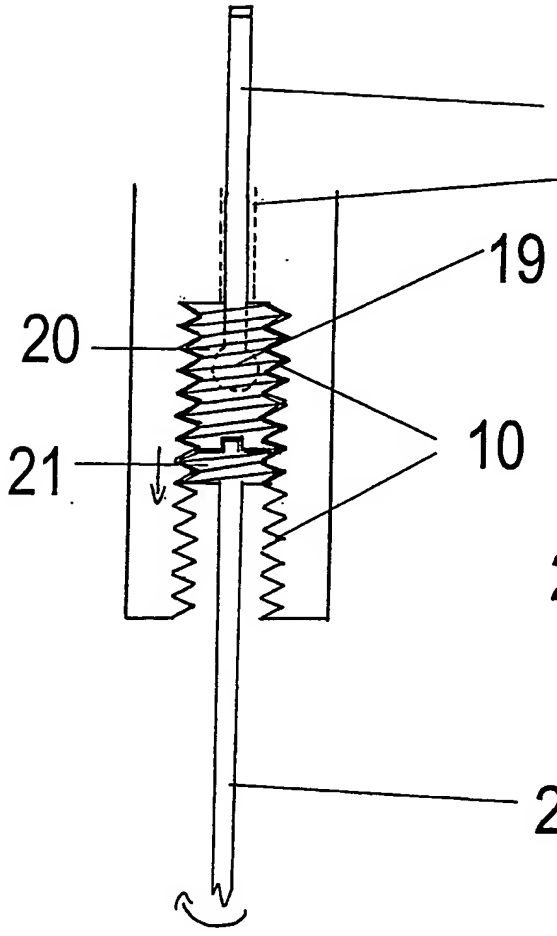

Fig. 14

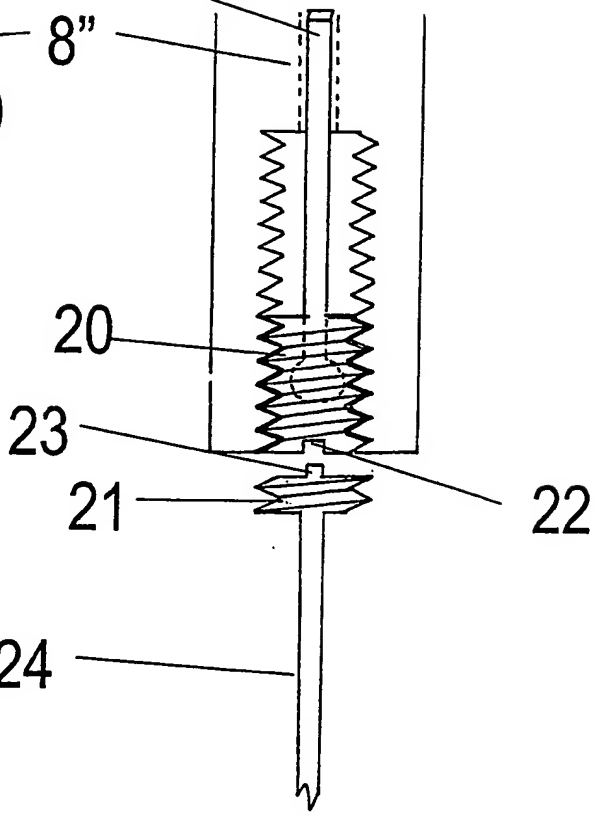

Fig. 15

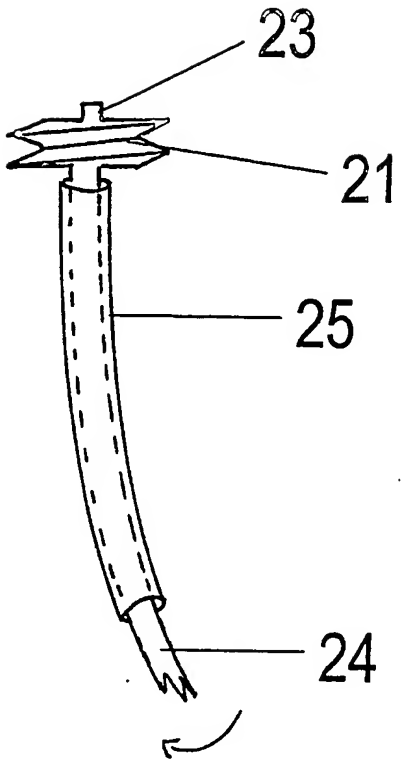

Fig. 16

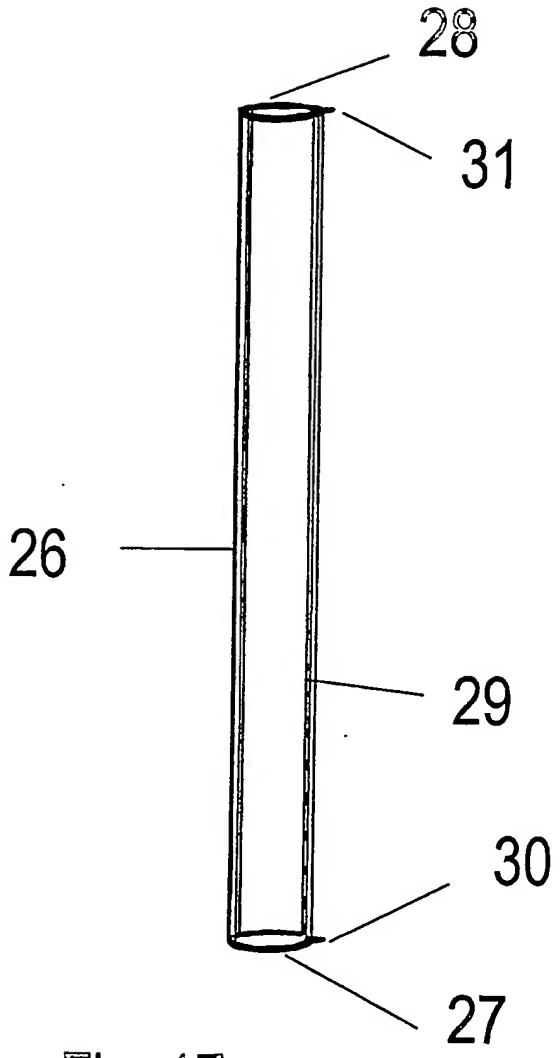

Fig. 17

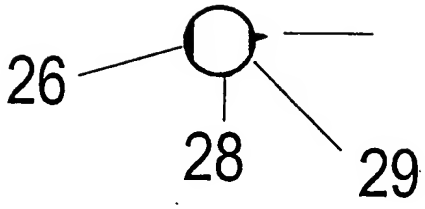

Fig. 18

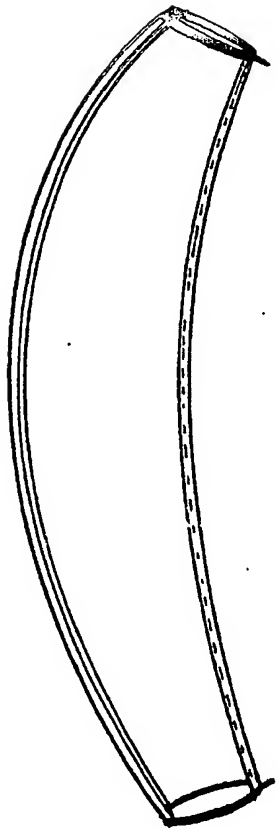

Fig. 19

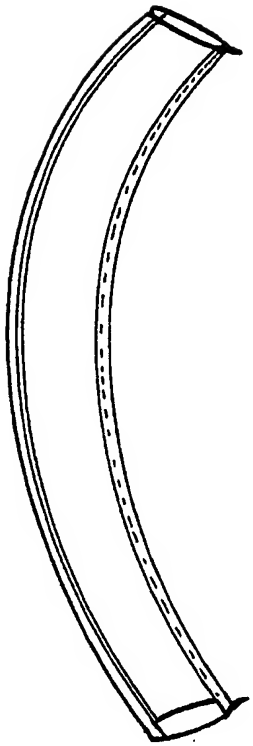

Fig. 20

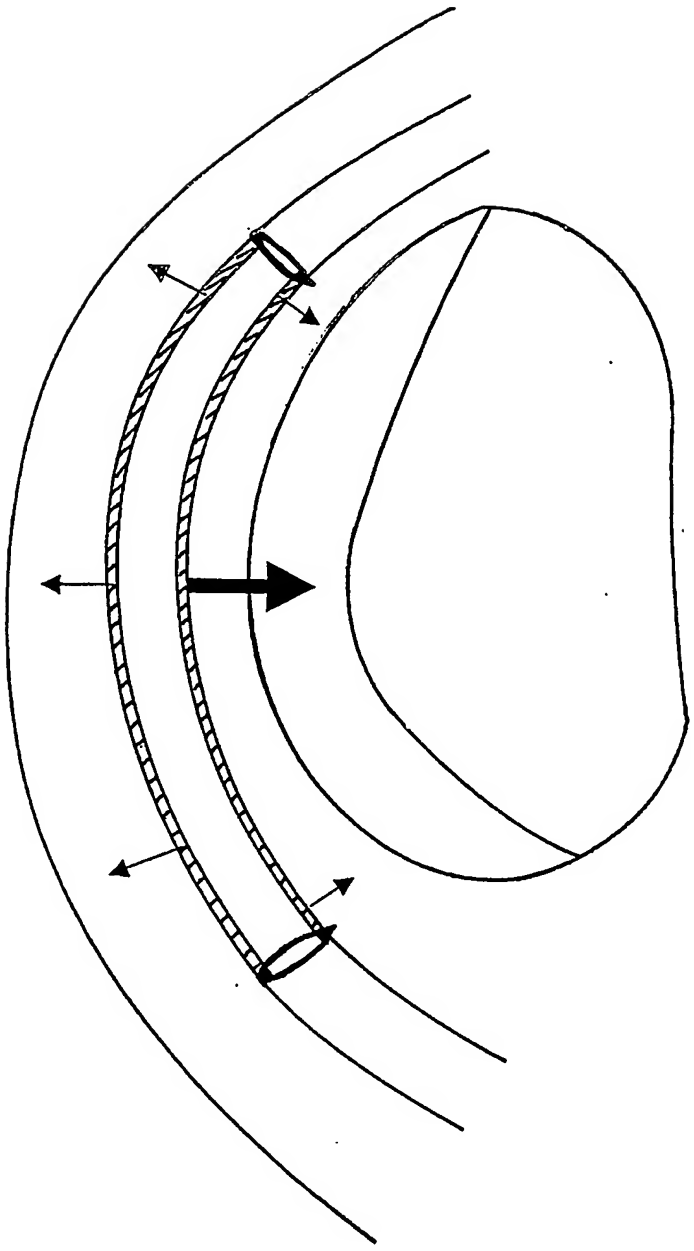

Fig. 21

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(74) Agents: **HEUCKEROTH, Volker** et al.; Witte, Weller & Partner, Postfach 105462, 70047 Stuttgart (DE).

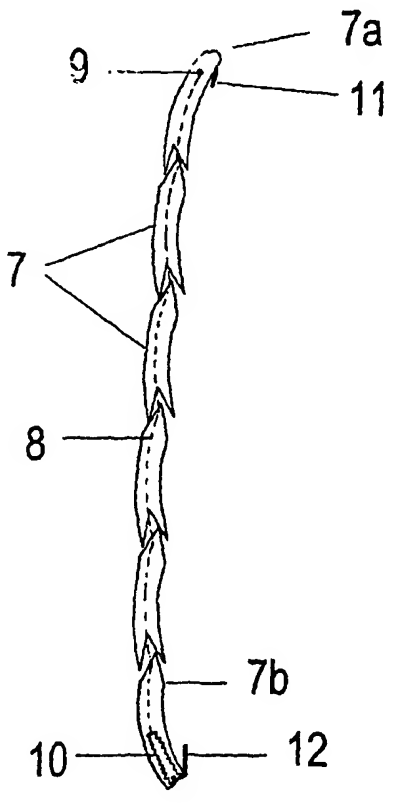
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: DEVICE FOR TREATMENT OF AN INSUFFICIENCY OF A HEART VALVE



(57) Abstract: The invention relates to a device for treatment of insufficiency of a heart valve comprising a longitudinal body (7-7) that can have at least two different forms, namely one easily introduced into the coronary sinus (5) or the great cardiac vein (vena cordis magna, 6) and to the vessel adaptable form, and a second one the position of the heart valve affecting form. The second form, when the longitudinal body (7-7) has been placed into the said vein, presses the vessel and thereby the orifice of the heart valve in parallel towards a closed position.

WO 2004/084746 A3

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
16 December 2004

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/003166

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/062263 A (VIACOR, INC) 15 August 2002 (2002-08-15)	1-3,5,7, 11,12, 15,16
Y	page 16, line 9 - page 18, line 8; figures 3-5	4,6,17
Y	US 2003/050693 A1 (QUIJANO ET AL.) 13 March 2003 (2003-03-13) abstract; figures 1-6	4,6,17
X	WO 02/078576 A (VIACOR, INC) 10 October 2002 (2002-10-10) page 35, line 20 - page 36, line 3; figure 10 page 41, line 10 - page 42, line 11; figures 17-20 page 43, line 14 - page 52, line 8; figures 25-37K	1-6,8, 14,15

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
1 November 2004	08/11/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

INTERNATIONAL SEARCH REPORT

national application No.
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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

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Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP2004/003166

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